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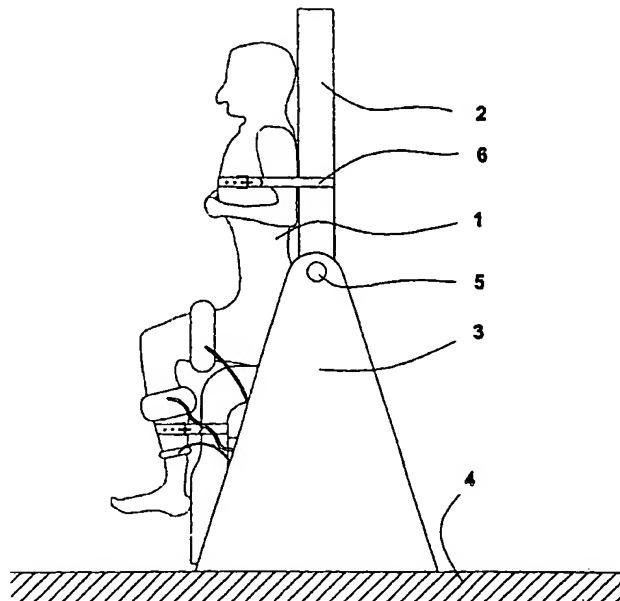
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(54) Title: METHOD AND APPARATUS FOR DIAGNOSING VENOUS DISEASE IN THE LOWER LIMBS



(57) Abstract: An apparatus for diagnosing the presence of venous disease in the lower extremities of a patient comprises a support for supporting the patient in an upright sitting position and a recumbent sitting position and plethysmographic means applicable to a distal leg portion. The support is disposed displaceable between these positions in either of which it can be secured. A corresponding method is also disclosed.

METHOD AND APPARATUS FOR DIAGNOSING VENOUS DISEASE  
IN THE LOWER LIMBS

FIELD OF THE INVENTION

5 The present invention relates to a method for diagnosing  
venous disease in the lower limbs of a patient and to  
corresponding apparatus. The present invention furthermore  
relates to an apparatus and a method for determining the  
correct pressure to be applied to a lower limb of a  
10 patient suffering from a corresponding venous disease by  
means of an elastic hosiery or bandage, and to such  
hosiery and bandage designed in accordance with the  
determined correct pressure.

15 BACKGROUND OF THE INVENTION

The malfunction of the valves of the large veins of the  
lower limbs results in the local accumulation of body  
fluids, and in impaired venous return. This condition  
20 constitutes a substantial risk for venous thrombosis.  
Thrombi formed in the lower limbs may come off and be  
carried by the blood stream to the lungs, thereby  
occluding the pulmonary blood vessels. This may disable  
the patient and even be lethal. Therefore a correct  
25 diagnosis of venous disease in a patient therefore is  
desirable.

Though venous disease in the lower limbs cannot be cured  
the condition of the patient can be substantially improved  
30 by mechanical means compensating for the malfunction of  
the valves of the large veins. These means comprise  
elastic support stockings, bandages, etc. to be applied to  
the patient's legs and/or thighs. Thereby accumulation of  
venous blood in the lower extremities is reduced or even

prevented, as is the risk of thrombosis in the lower extremities. These support means include a resilient material such as rubber. Expansion against the resilient force or the material when putting on a stocking or bandage results in corresponding pressure being exerted on the corresponding limb. They thus serve the purpose of compressing the portion(s) of the lower limbs where the defective large veins are located. Thereby the veins themselves become compressed and their valves put in a state where their function is substantially improved. A condition for optimal effect of such support means on venous return is the application of the correct external pressure at the respective portion of the limb. In this context "optimal external pressure" is the pressure maximizing venous return. The application of insufficient external pressure will only partially compensate for the defective valve function; in other words, an external pressure is considered to be insufficient as long as an incremental increase of it results in increased venous return. On the other hand, the external pressure must not be too high, since this would impair arterial function in the lower limbs which also translates to a reduced venous return. It should also be understood that there is a large variation between patients, and in the same patient in respect of a deteriorating or improving condition of venous disease, in regard of the external pressure required for optimal compensation of defective veins in the lower limbs.

While these principles are generally accepted, they do not seem to have been put to use. Support stockings and bandages are usually selected from a range of support items of same size covering a range of contractile strengths when expanded to the same extent, say 10%.

These support items are prescribed to a patient on a trial and error basis. There is a need for a method by which an support stocking, bandage and the like exerting an optimal support pressure when applied to the limb of a patient can  
5 be selected.

#### OBJECTS OF THE INVENTION

It is an object of the present invention to provide an  
10 apparatus for diagnosing the presence of venous disease in the lower extremities of a patient.

It is a second object of the present invention to provide a method for diagnosing the presence of venous disease in  
15 the lower extremities of a patient.

It is a third object of the present invention to provide an apparatus for determining the correct circulation support pressure to be applied to a lower limb of a  
20 patient suffering from a venous disease in the lower limbs by means of an elastic hosiery, bandage or the like.

It is a fourth object of the present invention to provide a method for determining the correct circulation support  
25 pressure to be applied to a lower limb of a patient suffering from venous disease in a lower limb by means of an elastic hosiery.

It is a fifth object of the present invention to provide a  
30 process for manufacturing or selecting a venous return support device to be applied to a lower limb of a patient suffering from venous disease.

Further objects of the invention will be evident from the following description of the invention and preferred embodiments thereof, and from the appended claims.

## 5 SUMMARY OF THE INVENTION

According to the present invention it disclosed an apparatus for diagnosing the presence of venous disease in the lower extremities of a patient, comprising:

- 10
- a support for supporting the patient in an upright sitting position and in a recumbent sitting position,
  - plethysmographic means applicable to a distal leg portion;

the support being disposed displaceable between said  
15 positions in either of which it can be secured. The apparatus preferably comprises means for securing the support in either position. The support may be displaced by hand or by electrical drive means between these positions.

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According to the present invention is also disclosed a method for diagnosing the presence of venous disease in the lower extremities of a patient, comprising the following consecutive steps:

- 25
- (a) positioning the patient in a first recumbent examination position on a support with the body and the legs in a horizontal position and the thighs in a vertical position;
  - (b) recording an external dimension of a first portion  
30 of a leg in said first examination position;
  - (c) rotating the patient by about 90° to a second upright sitting examination position;

- (d) recording said external dimension in said second examination position;
- optionally repeating steps (a)-(d);
- relating the recorded values to a standard.

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According to a first preferred aspect of the invention steps (e,f) are followed by an exercise step in which the patient is made to move the corresponding foot forwards and backwards between a dorsiflexion position and a  
10 plantar flexion position while recording the pressure. In a healthy person the pressure will thereby made to approach the pressure in the recumbent position whereas, in a person with venous disease, the pressure will oscillate at about the level of the first force.

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It is preferred for the method to include in the second examination position a period of physical exercise in which the patient is made to move the corresponding foot forwards and backwards between a dorsiflexion position an  
20 a plantar flexion position while recording said external dimension. In a healthy person the external dimension will thereby made to approach the dimension in the first examination position whereas, in a person with venous disease, the dimension will oscillate at about the level  
25 of the second examination position.

The present invention is also disclosed an apparatus for determining the correct circulation support pressure to be applied to a lower limb of a patient suffering from a  
30 venous disease in the lower limbs by means of an elastic hosiery or bandage, comprising:

- a support for supporting the patient in an upright sitting position and in a recumbent sitting position;

- plethysmographic means applicable to a leg portion;
- first compression cuff means applicable to a leg portion proximal of the plethysmographic means and/or second compression cuff means applicable to a thigh portion.

5

It is within the scope of the present invention for the cuff means to comprise several adjacent cuffs, the pressure of which may be selectively or integrally controlled. It is also within the scope of the invention to control the plethysmographic means, the first cuff means and, if present, the second cuff means, by microprocessor means.

According to the invention is also disclosed a method for determining the correct circulation support pressure to be applied to a lower limb of a patient suffering from venous disease in a lower limb by means of an elastic hosiery, bandage or the like, comprising:

- (a) positioning the patient in a first recumbent examination position on a support with the body and the legs in a horizontal position and the thighs in a vertical position;
- (b) recording the variation of an external dimension of a first portion of a leg or thigh;
- (c) keeping the patient in said examination position until the variation of said external dimension has essentially ceased;
- (d) essentially restricting the blood flow in the limb by inflation of restriction means disposed proximally of said examination position;
- (e) rotating the patient by about 90° to a second upright sitting examination position;

- (f) recording said external dimension of said first portion;
  - (g) releasing fluid from said restriction means;
  - (h) reading the pressure at which said external
- 5        dimension begins to increase which is which is the correct support pressure to be applied to said lower limb.

According to the invention is also disclosed a process for  
10    manufacturing or selecting a venous return support device to be applied to a lower limb of a patient suffering from venous disease, comprising:

- determining an optimal support pressure at the portion of the lower limb to which the support device is
- 15        intended to be applied;
- manufacturing or selecting a support device providing the required optimal support pressure.

The pressure necessary for compensation of defective  
20    valves of the large veins of the lower limbs varies from about 20 mm of Hg for a healthy person to about 60 mm of Hg and more for a person with manifest venous disease.

According to a second preferred aspect of the invention is  
25    disclosed a station for examination of the peripheral circulation of a patient, comprising a console, a back rest portion mounted rotatably on the console, a seat mounted rotatably on the back rest portion, an arm assembly mounted rotatably on the back rest portion near  
30    its one proximal end and being extendable in a distal direction and having rotatably mounted near its distal end a foot and heel support portion, the rotation of said back rest, said seat, said arm assembly and said foot and heel



support portion by electric motors being controlled by a control unit comprising a computer and dedicated software.

It is preferred for arm assembly to comprise telescopic extension means. It is also preferred for the arm assembly to comprise means, such as brackets, for mounting of leg cushions. It is furthermore preferred for the arm assembly and/or the console to comprise connectors for strain gauges and/or pneumatic connectors and or connectors for ultrasound scanning, in particular Doppler or duplex scanning and/or connectors for pulse rate measurement and similar.

It is preferred for the examination station to comprise an emergency stop, preferably one operable by the patient. It is furthermore preferred for the examination station to comprise hand rail which can be swiveled between two positions, one of the allowing the patient to sit down on the seat or the stand up from it, the other locking the patient in a sitting position; the patient may grasp the hand rail during examination, in particular during a change in position.

#### DESCRIPTION OF THE DRAWINGS

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The invention will now be described in more detail by reference to a rough drawing illustrating in:

Fig. 1 a schematic view of a first embodiment of the apparatus of the invention for determining an optimal support pressure for elastic hosiery with a patient suffering from venous disease in a recumbent position;

Fig. 2 the embodiment of Fig. 2, with the patient in

- a sitting position, in the same view as in Fig. 1;
- Fig. 3 an enlarged partial view of Fig. 2;
- Fig. 4 a diagram showing plethysmograph traces from  
5 diagnostic experiments with healthy and diseased persons;
- Fig. 5 a diagram showing a plethysmograph trace from an experiment for determining the optimal support pressure for elastic hosiery intended for  
10 supporting a leg of a patient suffering from venous disease;
- Fig. 6 a station for examination of the peripheral circulation of a patient comprising a patient support, in a perspective view;
- 15 Fig. 7(a)-(d) the station of Fig. 6 with the patient support in four different positions, in a side view.

#### DESCRIPTION OF PREFERRED EMBODIMENTS

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A preferred embodiment of the apparatus of the invention for determining an optimal support pressure for elastic hosiery with a patient suffering from venous disease shown in Figures 1-3 comprises a support in the form of a light-  
25 weight chair-like element 2 comprising a reinforced polystyrene shell filled with rigid polyurethane foam and a transverse metal shaft 5 disposed near the center of gravity (in a longitudinal direction). The chair-like element 2 is rotatably supported in a metal frame 3.

30 Electrical drive means for turning the chair-like element between a vertical position (Fig. 1) and a horizontal position (Fig. 2) and mechanical means for securing it in these extreme positions are disposed inside of the metal frame 3 and not shown. A patient 1 sitting on the support

(Fig. 1) is secured to the support by belts 6. In Fig. 2 the support with the patient is shown in a horizontal position.

5 The following devices are arranged at the left lower limb of the patient 1: a plethysmographic sensor 10 enclosing the leg 8 at about its distal third; a first pressure cuff 13 enclosing the leg at about the center of the leg 8; a  
10 second pressure cuff 16 disposed at about the center of the thigh 7. The devices 10,13,16 are connected to corresponding control units 12,15,18 by a cable 11 and flexible tubes 14,17, respectively. The plethysmographic sensor 10 records changes in the circumference of the leg at a site where body fluid (blood and lymph)  
15 preferentially accumulates in patients with venous disease in their lower limbs. The air pressure in the cuffs 13,16 is controlled by respective control units 15,18, respectively, comprising air pumps, three-way control valves and pressure sensors. Instead of air pumps the air  
20 or other gas used for inflation can be drawn from gas cylinders or lines for supply of compressed air often found in hospitals. The control units 12,15,18 are in communication with a central microprocessor unit 19 connected to a display and a keyboard (not shown) for  
25 input of instructions by the physician or other person carrying out the clinical investigation. The microprocessor runs on state of the art software developed for the specific purpose. Input and output data are be stored in the permanent memory of the microprocessor and  
30 may be printed out on request.

Another preferred embodiment of the invention comprising an apparatus for diagnosing the presence of venous disease in the lower extremities of a patient does not make use of

pressure cuffs. It is thus represented by an apparatus corresponding to that described above but lacking the first and second cuffs and the corresponding control units.

5

In the method of the invention for diagnosing the presence of venous disease in the lower extremities, the patient NN is made to sit on the upright positioned support and fastened with belts 4. (Alternatively, the patient may be made to lie on the horizontally positioned support and fastened with belts in this position.) A plethysmographic sensor 10 for continuous recording of the circumference of a leg is applied to the left leg of the patient at about its distal third. This position is shown in Fig. 1. The support 2 with the patient 1 then is rotated by 90° to the horizontal position shown in Fig. 2 in which the support is secured. Plethysmographic recording is started, and the patient is allowed to rest for a couple of minutes which is sufficient for stabilizing the circumference reading shown in Fig. 4 (Period A) at a. At time B the support with the patient is rotated back to the sitting position in which it is secured and allowed to remain for the rest of the clinical investigation. The plethysmographic recording indicates a substantial increase in circumference within a short time leveling off at c (period C). Upon the reading having stabilized the patient is told (at D) to flex the foot of the leg under investigation fourth and back between a dorsiflexion position and a plantar flexion position. The plethysmographic recording during this period (E) shows the circumference oscillating at about level c in phase with the flexing movement. When repeated with a healthy person MM the circumference rises substantially less (to level b) in phase C than in the diseased person NN. Also,

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the behavior in phase E is different: the center of the oscillations declines toward the initial circumference level a, indicating a proper function of the venous valves.

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Fig. 5 illustrates an aspect of the invention relating to a method for determining the correct circulation support pressure to be applied to a lower limb of a patient suffering from venous disease in a lower limb by means of an elastic hosiery, bandage or the like. In the same manner as described above the patient is secured to the rotatable support; in addition of being provided with the plethysmograph sensor an inflatable cuff 13 is put around the patient's left leg 8 at about its center. The patient is then brought into the recumbent position (Fig. 2) and the plethysmographic recording started. After the circumference having stabilized at a level corresponding to a in Fig. 4 the cuff is inflated to a pressure exceeding 60 mm of Hg. The patient then is brought back in the upright position (Fig. 1) and the cuff is slowly deflated (Fig. 5, period R). At a certain pressure S the circumference starts to increase (period T). The pressure S is the correct pressure to be applied to the patient's leg for providing optimal support to the compromised valves of the large veins, in particular the anterior and posterior tibial veins.

The value S can be used to select an elastic hosiery (stocking) of proper size from a set of stockings covering a range of S values. With proper size is understood a non-expanded size which, upon expansion when being disposed on the selected portion of the leg or thigh, exerts a pressure S.

30

A third preferred embodiment of the apparatus of the invention is illustrated in Figs. 6 and 7. This embodiment, which is a station for examining peripheral circulation may comprise some or all of the features of the aforementioned embodiments. The examination station 100 has the form of a seat comprising a back rest 101, a seat 102 and foot and heel support 103. In the starting position the elements 101, 102, and 103 are positionally related to each other as the corresponding elements of a seat with a foot support used in, for instance, air planes. In this starting position the patient seats down on the seat 102 while resting with his back against the back rest 101, and places his feet on the foot and heel support 103. The elements 101 - 103, termed patient support in combination, are rotatably disposed with regard to each other and with regard to a console 104 provided with wheels 105 to make it displaceable on the floor of the examination room. The back rest 101 comprises a support frame 106 rotatably fixed to the console 104 via a first axle 107 indicated in Fig. 7(a). The seat 102 is rotatably fixed to the support frame 106 by the same axle 107. A hollow arm 110 on which leg cushions 111 can be mounted via mounting brackets 112 is rotatably fixed near its proximal end at the support frame 106 by a second axle 108. From its distal end emerges a telescopically displaceable rod 120 at the distal end of which the foot and heel support 103 is swivelingly fixed by a third axle 113. The elements 101 - 103 can be rotated in respect of each other and/or in respect of the console 104 by means of electric motors (not shown) mounted inside of the support frame 106 and inside and adjacent to the distal end of the arm section 110. The telescopically displaceable rod 120 is also powered by an electric motor (not shown). The electric motors are controlled by a

computer 109 disposed on (preferably) the right hand side of the examination station 100. Also shown in Fig. 6 are strain gauge connectors 115 and pneumatic connectors 116 disposed on the arm 110 and the console 104, respectively.

5 A control panel 118 is disposed adjacent to the computer 109.

Fig. 7 illustrates various positions which the patient support 101, 102, 103 can take. In the starting (home) position (a) the arrangement of the patient support is similar to that in a chair with a foot support. In the "laying-seat" position (b) the back rest 101 has been rotated backwards by about  $85^\circ$  to assume a nearly horizontal position while the seat 102 has been rotated backwards (upwards) by about  $75^\circ$  and the arm section 110 has been rotated backwards (upwards) by about  $165^\circ$  while keeping fixed its rotational relationship with of the foot and ankle support portion 103. In the "flat" position (c) the support portions 101 - 103 are disposed horizontally in the same plane. In the "bent" position (e) the back rest 101 is disposed horizontally while the seat 102 and the foot and heel support 103 and the cushion 111 are disposed in a plane deviating from the horizontal by about  $-15^\circ$ . The angle formed between elements 101 and 102 as seen from the patient's side is about  $75^\circ$  in position (a), about  $105^\circ$  in position (b), about  $180^\circ$  in position (c) and about  $195^\circ$  in position (d). These positions are controlled by a program stored in the computer 109. In addition to these "fixed" positions it is also possible to realize other angular positions by manually feeding the corresponding angle values to the computer or by programming the computer accordingly.

The apparatus is furthermore provided with a U-formed hand rail 114 fixed at the respective sides of the back rest 101, which the patient holds during examination, in particular when the seat is quickly tilted or moved back to an upright position. The hand rail 114 is swivelingly mounted in the back rest 101 at 119 in a way that allows its base to be displaced between two extreme positions, one behind the patient's head (in relation to a patient sitting in the seat), which allows the patient to rise, and another, in which it can be locked so that its base is located in front of the patient's body.

The apparatus is provided with an emergency stop 117 which can be operated by the patient. The software of the computer may comprise means for mathematical treatment of the measurements, for displaying of the results and for storing and/or printing them. In addition to pletysmographic means other means which are suitable for the examination of peripheral circulation of a patient may be used with the apparatus of the invention and be connected with it or integrated in it, such as means for Doppler or duplex ultrasound scanning, heart rate measurement, oxygen consumption measurement, etc.

The control panel 118 comprises the following functions: movement of the seat up and down; tilting the seat between laying and sitting positions; adjustment of leg support up and down; adjustment of the length of leg support (by telescopic rod 120); quick tilting from laying to sitting position; disposition of elements 101 - 103 in the modes illustrated in Fig. 7 (a) "home", (b) "laying seat", (c) "flat", (d) "bent"; return to start (home) position. If the alarm (emergency) button 117 is pressed (and thereby locked) all movements stop immediately. The emergency



button has to be released before any new movements can be carried out.

## C l a i m s

1. An apparatus for diagnosing the presence of venous disease in the lower extremities of a patient, comprising:

- 5     • a support for supporting the patient in an upright sitting position and in a recumbent sitting position,
- plethysmographic means applicable to a distal leg portion;

      the support being disposed displaceable between said  
10   positions in either of which it can be secured. The apparatus preferably comprises means for securing the support in either position. The support may be displaced by hand or by electrical drive means between these positions.

15

2. A method for diagnosing the presence of venous disease in the lower extremities of a patient, comprising the following consecutive steps:

- (a) positioning the patient in a first recumbent  
20   examination position on a support with the body and the legs in a horizontal position and the thighs in a vertical position;
- (b) recording an external dimension of a first portion of a leg in said first examination position;
- 25   • (c) rotating the patient by about 90° to a second upright sitting examination position;
- (d) recording said external dimension in said second examination position;
- (e) optionally repeating steps (a)-(d);
- 30   • (f) relating the recorded values to a standard.

3. The method of claim 2, wherein steps (e,f) are followed by an exercise step in which the patient is made to move

the corresponding foot forwards and backwards between a dorsiflexion position and a plantar flexion position while recording the pressure. In a healthy person the pressure will thereby made to approach the pressure in the  
5 recumbent position whereas, in a person with venous disease, the pressure will oscillate at about the level of the first force.

4. The method of claim 2 or 3, including, in the second  
10 examination position, a period of physical exercise in which the patient is made to move the corresponding foot forwards and backwards between a dorsiflexion position and a plantar flexion position while recording said external dimension.

15

5. The method of claim 4, comprising identifying in a person with venous disease by said external dimension oscillating at about the level of the second examination position.

20

6. An apparatus for determining the correct circulation support pressure to be applied to a lower limb of a patient suffering from a venous disease in the lower limbs by means of an elastic hosiery or bandage, comprising:  
25 • a support for supporting the patient in an upright sitting position and in a recumbent sitting position;  
• plethysmographic means applicable to a leg portion;  
• first compression cuff means applicable to a leg portion proximal of the plethysmographic means and/or second  
30 compression cuff means applicable to a thigh portion.

7. The apparatus of claim 6, wherein the cuff means comprise several adjacent cuffs, the pressure of which may be selectively or integrally controlled.
- 5 8. The apparatus of claim 6 or 7, comprising microprocessor means for control of the pletysmographic means, the first cuff means and, optionally, the second cuff means.
- 10 9. A method for determining the correct circulation support pressure to be applied to a lower limb of a patient suffering from venous disease in a lower limb by means of an elastic hosiery, bandage or the like, comprising:
- 15 • (a) positioning the patient in a first recumbent examination position on a support with the body and the legs in a horizontal position and the thighs in a vertical position;
- (b) recording the variation of an external dimension of  
20 a first portion of a leg or thigh;
- (c) keeping the patient in said examination position until the variation of said external dimension has essentially ceased;
- (d) essentially restricting the blood flow in the limb  
25 by inflation of restriction means disposed proximally of said examination position;
- (e) rotating the patient by about 90° to a second upright sitting examination position;
- (f) recording said external dimension of said first  
30 portion;
- (g) releasing fluid from said restriction means;
- (h) reading the pressure at which said external dimension begins to increase which is which is the

correct support pressure to be applied to said lower limb.

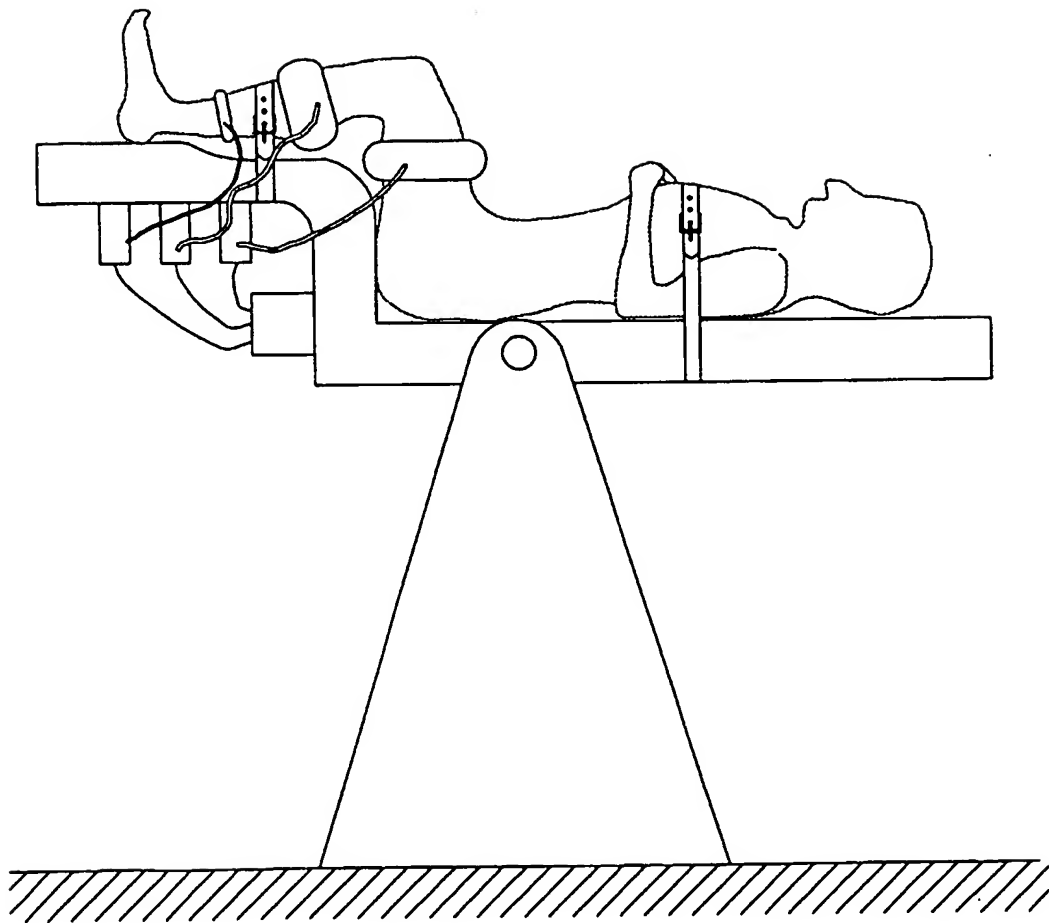
10. A process for manufacturing or selecting a venous  
5 return support device to be applied to a lower limb of a patient suffering from venous disease, comprising:

- determining an optimal support pressure at the portion  
of the lower limb to which the support device is  
intended to be applied;
- 10 • manufacturing or selecting a support device providing  
the required optimal support pressure.

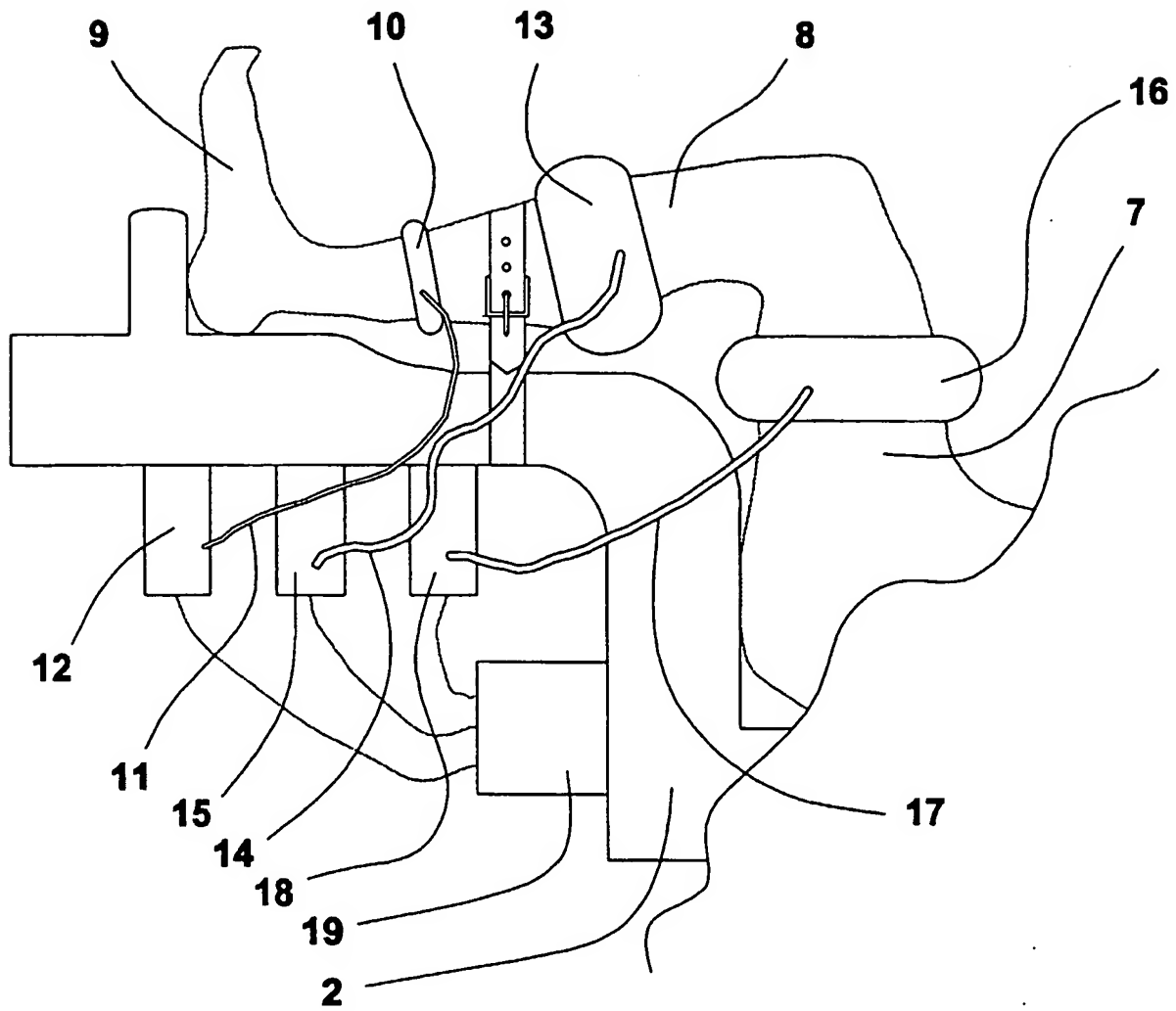
11. The process of claim 10, wherein said optimal support  
pressure is from about 20 mm of Hg for a healthy person to  
15 about 60 mm of Hg for a person with manifest venous  
disease.

12. A station for examination of the peripheral  
circulation of a patient, comprising a console, a back  
20 rest portion mounted rotatably on the console, a seat  
mounted rotatably on the back rest portion, an arm  
assembly mounted rotatably on the back rest portion near  
its one proximal end and being extendable in a distal  
direction and having rotatably mounted near its distal end  
25 a foot and heel support portion, the rotation of said back  
rest, said seat, said arm assembly and said foot and heel  
support portion by electric motors being controlled by a  
control unit comprising a computer and dedicated software.



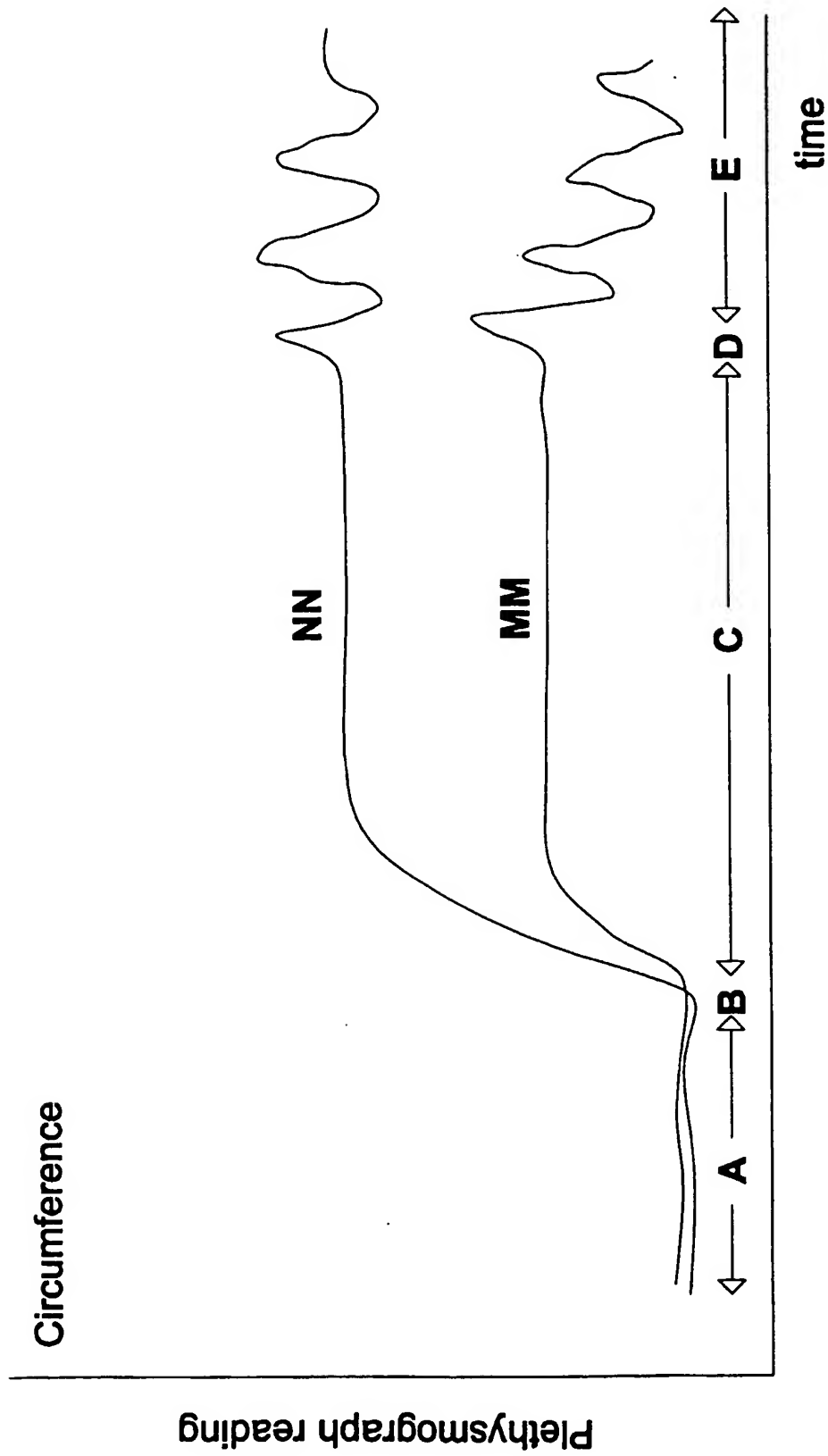


**Fig. 2**

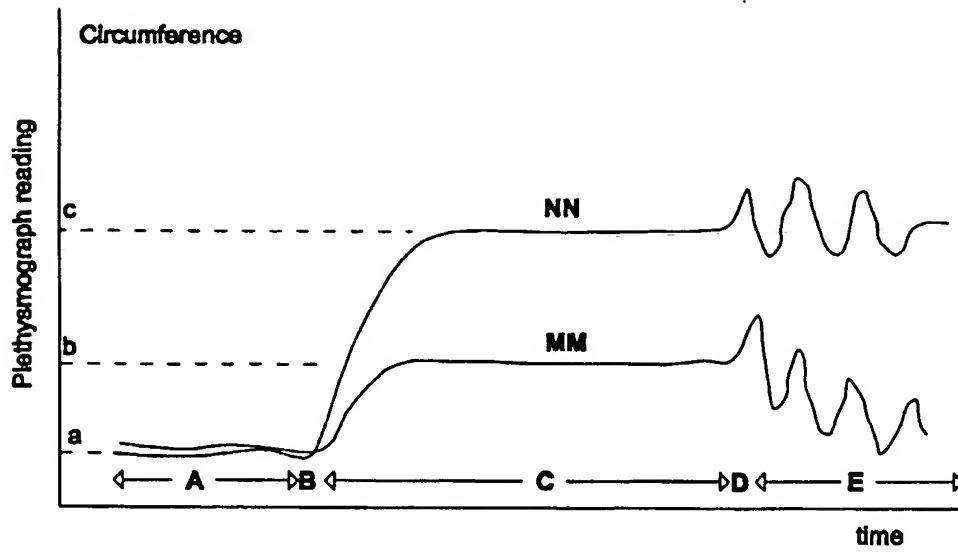
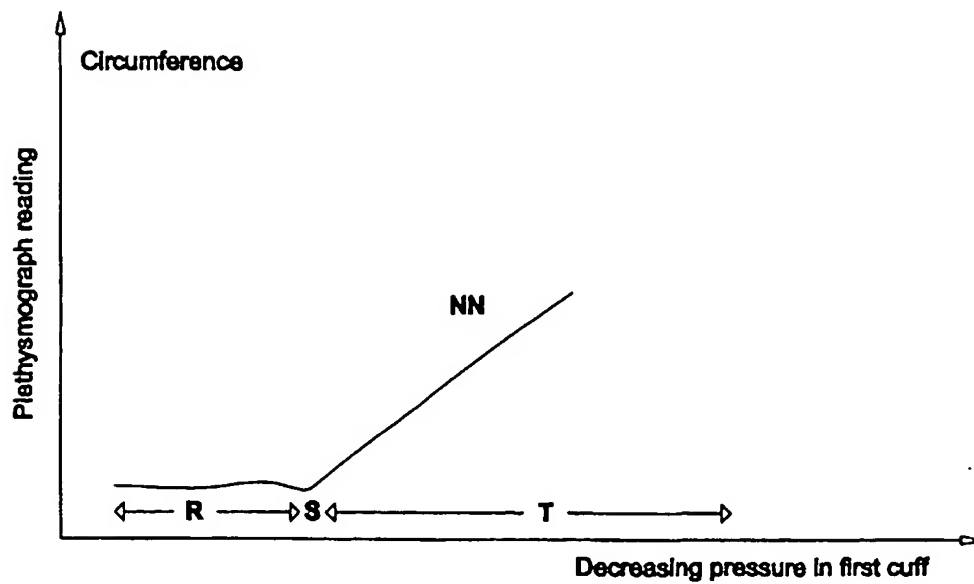


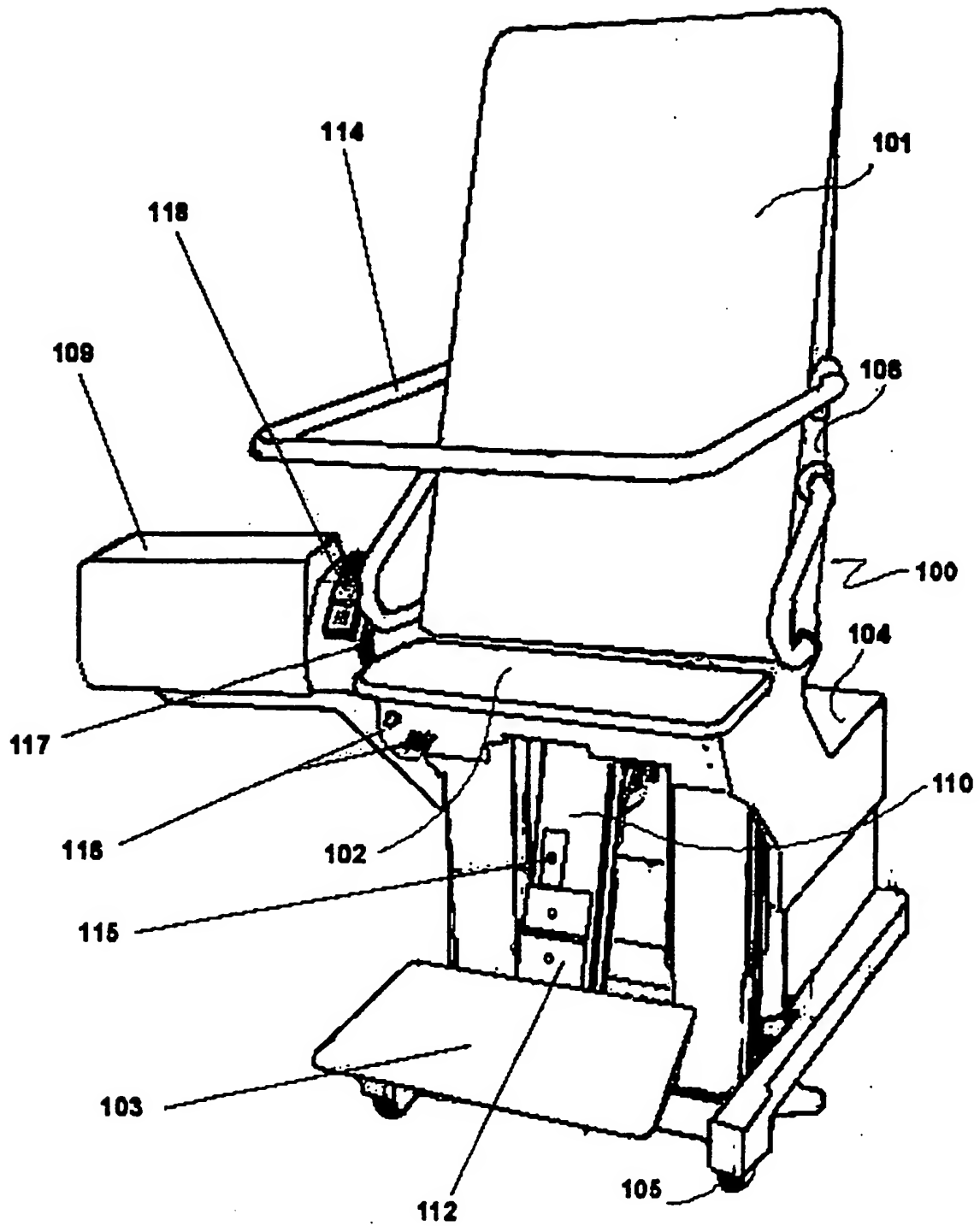
**Fig. 3**



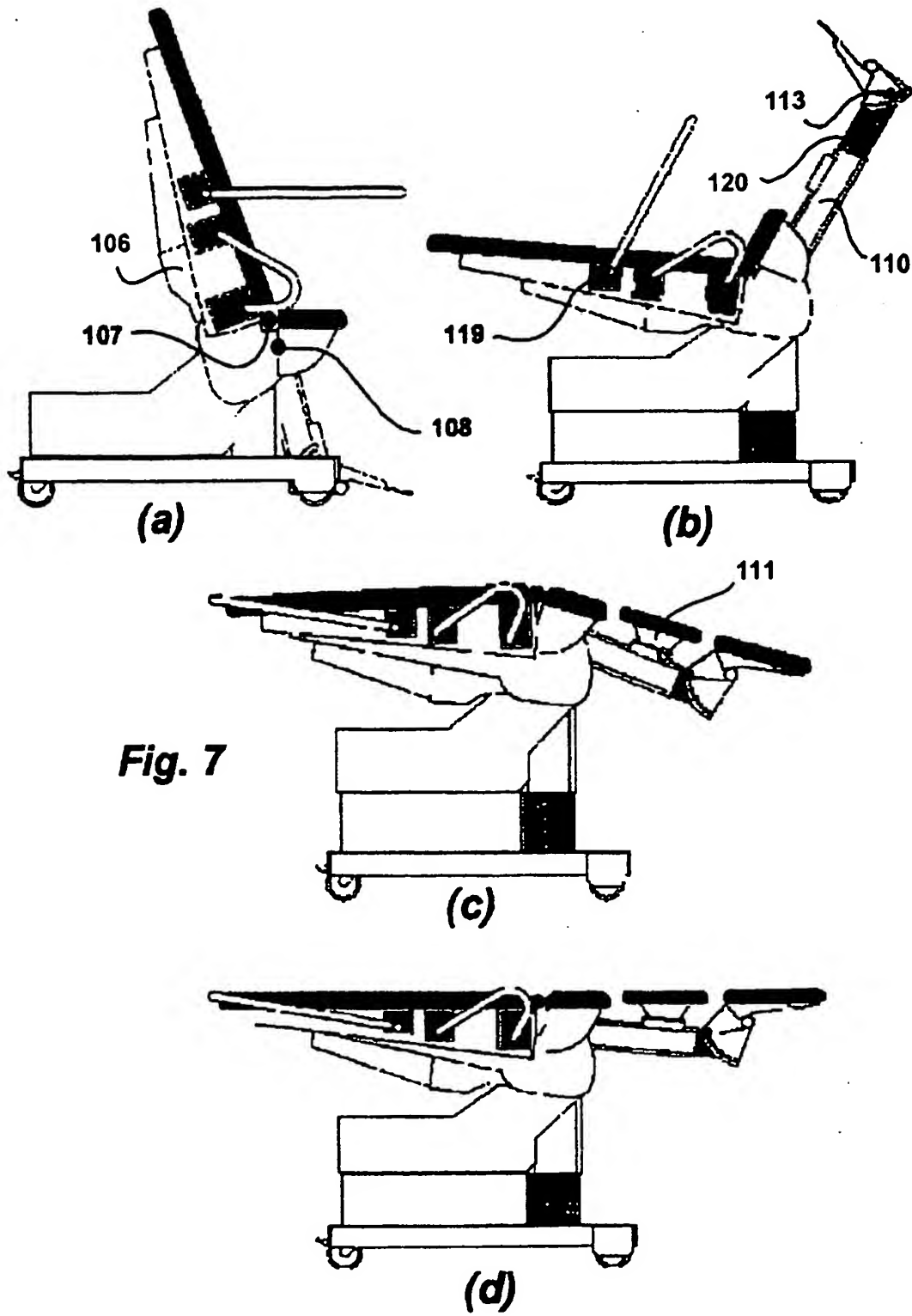


**Fig. 4**

**Fig. 4****Fig. 5**



**Fig. 6**



## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/00715

## A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/103, A61B 5/107

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, INSPEC

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<b>DATABASE WPI</b> Week 198815 Derwent Publications Ltd., London, GB; Class P31, AN 1988-104194 & SU 1337043 A(ROST MED INST), 15 September 1987 (1987-09-15) abstract --	1-12
A	<b>DATABASE WPI</b> Week 199208 Derwent Publications Ltd., London, GB; Class P31, AN 1992-063188 & SU 1651854 A(PHYSICAL CULTURE), 30 May 1991 (1991-05-30) abstract --	1-12

☒ Further documents are listed in the continuation of Box C.
☒ See patent family annex.

<ul style="list-style-type: none"> <li>* Special categories of cited documents:</li> <li>"A" document defining the general state of the art which is not considered to be of particular relevance</li> <li>"E" earlier application or patent but published on or after the international filing date</li> <li>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</li> <li>"O" document referring to an oral disclosure, use, exhibition or other means</li> <li>"P" document published prior to the international filing date but later than the priority date claimed</li> </ul>	<ul style="list-style-type: none"> <li>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</li> <li>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</li> <li>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</li> <li>"&amp;" document member of the same patent family</li> </ul>
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Date of the actual completion of the international search
Date of mailing of the international search report

12 August 2003

14 -08- 2003

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 03/00715

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	BOSHOV, V.M. ET AL: Rheplasthysmography in lower extremities deseases diagnostics. Proceedings of the 8th annual Conf of the IEEE/Engineering in Medicine and Biology Society (Cat No.86 CH2368-9), Conf Article, Publ. 1986, New York,USA. See abstract --	1-12
A	US 4169463 A (PIQUARD, J.-F.), 2 October 1979 (02.10.79), figure 3, abstract --	1-12
A	GB 1574869 A (MEDICOR MUVEK), 10 Sept 1980 (10.09.80), figure 1, claim 1 --	1-12
A	US 4548211 A (MARKS, L.A.), 22 October 1985 (22.10.85), figure 1, abstract -- -----	1-12

## INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/SE03/00715****Box I** Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **2-5**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**see extra sheet**
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II** Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

## Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/SE03/00715**

Continuation of Box 1.

Claims 2-5 relates to a method for diagnosing a human or animal body. Thus the International Search Authority is not required to carry out an international search for these claims (Rule 39.1 (iv)). Nevertheless, a search has been executed for claims 2-5.



## INTERNATIONAL SEARCH REPORT

Information on patent family members

26/07/03

International application No.

PCT/SE 03/00715

Patent document cited in search report			Publication date	Patent family member(s)	Publication date
US	4169463	A	02/10/79	FR 2354744 A,B	13/01/78
GB	1574869	A	10/09/80	CS 209806 B	31/12/81
				DD 132403 A	27/09/78
				DE 2751004 A,B,C	24/05/78
				ES 464181 A	16/12/80
				GR 64026 A	18/01/80
				HU 173760 B	28/08/79
				NL 7712555 A	19/05/78
				PL 112328 B	31/10/80
				PL 202209 A	03/07/78
US	4548211	A	22/10/85	NONE	

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